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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,011	02/26/2002	J. P. Bourguignon	37522-1001C2	3397

23910 7590 04/06/2005

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/087,011

Applicant(s)

BOURGUIGNON, J. P.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-29 is/are pending in the application.
- 4a) Of the above claim(s) 2-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/549798.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04/19/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 2-29 are pending. In response to restriction requirement, applicant elected Group III, and amended claims 16, 27-29 to read on the elected invention. Claims 2-13 are withdrawn from consideration, 37 CFR 1.142(b) as being drawn to a non-elected groups.

As per election of species, (1-3)IGF-1 is elected as a peptide antagonist. Claims reading on the elected species are 14-17,19-23,25-27, claims 14-17,20-23,25-27 being generic. Claims 18,24,28 are withdrawn from consideration as being drawn to non-elected species. Claims 14-17,19-23,25-27 are addressed to the extent they are directed to the elected species.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14-17,19-23,25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is made for the following reasons:

A. Claims 14-17,19-23,25-27 are rendered vague and indefinite by the language "method for influencing" used in claims 14-17, 20. "Influence" is a relative term, it is not defined by the claim, the specification does not provide a standard for ascertaining the

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requisite effect to constitute "influence", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear whether "influence" constitutes effect on receptor activity (inhibition or augmentation?), or effect on binding to the receptor, or effect on receptor internalization, etc. The same considerations apply to the use of the phrase "influence" in claims 16,17.

B. Claims 14-17,19-23,25-27 are rendered vague and indefinite by the language "at receptor" used in claims 14, 15, 18. Does it mean direct inhibition of receptor activity, or inhibition of events happening in front of receptor, or inhibition of events preceding involvement of the receptor, etc?

C. Claims 14-17, 20, 22, 24-28 are rendered vague and indefinite by the language "peptide antagonists". It is not defined antagonists of what are being used.

D. Claims 25,26: the claims lack antecedent basis as the previous claims do not recite any "medicament".

### **Claim Rejections - 35 USC § 102.**

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 14-17,19-23,25-27 are rejected under 35 U.S.C. 102(b) as anticipated by Sara et al. (Biochim. Biophys. Res. Commun., 165, 766-771, 1989).

Sara et al teach that N-terminal tripeptide fragment of IGF-1 (the reference addresses it as GPE, which is equivalent to instantly claimed (1-3)IGF-1) inhibits glutamate binding to NMDA receptor (see abstract and Fig.1). As such, the (1-3) IGF-1 is a peptide antagonist. As binding of glutamate to NMDA receptors evokes neurotransmitter release (see Linn et al, for example), by inhibiting binding to NMDA-receptors, (1-3) IGF-1 would also inhibit NMDA receptor-mediated effects.<sup>1</sup> The reference anticipates instantly claimed method of influencing NMDA-receptor controlled cells (or, as NMDA receptors are subset of glutamate receptors, influencing glutamate-receptor controlled cells).

In regard to claims 19-23,25-27,29, the language "for influencing" or "for treatment" is directed to intended use limitations which do not have patentable weight.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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<sup>1</sup> Note that stimulatory effect of GPE on acetylcholine release described in the reference is not addressed as NMDA receptor-mediated event. GPR potentiated potassium-induced acetylcholine release which has different mechanism (see p. 770, end of first paragraph).

5. Claims 14-20, 22, 24- are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U. S. Patent No.5,804,550. The claims of '550 are directed to methods of effect on glutamate and NMDA receptors and treatment of hypoxic brain disorders.


***Conclusion.***

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631

mlb